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1 10812380RECORD OF ORAL HEARING
2
3 UNITED STATES PATENT AND TRADEMARK OFFICE
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5
6 BEFORE THE BOARD OF PATENT APPEALS
7 AND INTERFERENCES
8

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10 *Ex parte* IFTIKHAR KHAN, and NAZIR KHAN
11

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13 Appeal 2010-003194
14 Application 10/812,380
15 Technology Center 3700
16

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18 Oral Hearing Held: July 22, 2010
19

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21 Before WILLIAM F. PATE III, STEVEN D. A. MCCARTHY and
22 MICHAEL W. O'NEILL, *Administrative Patent Judges*.
23
24

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1 The above-entitled matter came on for hearing on Thursday, July 22,
2 2010, commencing at 9:01 a.m., at the U.S. Patent and Trademark Office,
3 600 Dulany Street, Alexandria, Virginia, before Dawn A. Brown, Notary
4 Public.

5 THE USHER: Good morning. Calendar Number 39, Appeal Number
6 2010-003194. Mr. Khan.

7 JUDGE PATE: Okay. Thank you, Pat.

8 Good morning, Mr. Khan -- Dr. Khan. We have looked at this case
9 beforehand so we think we're up to speed on the technology, and we'd like to
10 hear your arguments concerning patentability. Just step up to the podium.

11 DR. KHAN: Here? There?

12 JUDGE PATE: Start there up at the podium.

13 DR. KHAN: Okay.

14 JUDGE PATE: Go ahead, sir.

15 DR. KHAN: My name is Khan. I'm one of the inventors of this invention.
16 This invention is an arteriovenous shunt whereby the blood from the artery
17 is taken to the dialysis machine, and from the dialysis machine, it is sent
18 back to the patient.

19 Now, going into the background, in 1976, a shunt was produced whereby the
20 artery is connected to the vein, it is sutured, and the material that he used is
21 called PTFE graft. When the blood goes from the high-pressure system
22 through the artery to the vein, it is of low pressure.

23 JUDGE PATE: Sure.

24 DR. KHAN: This vein wall is very thin and it reacts. And when it reacts, it
25 forms a tissue inside, and that usually blocks the graft resulting in the failure
26 of the graft. And this accounts for 80 percent of the cases. So the patient

1 success rate of the graft decreases by 60 percent the first year and by 20
2 percent in the third year.

3 So knowing that problem which remained unsolved, the other author,
4 Squitieri, he realized this complication. Well, he tried to put the graft
5 connecting to the artery into the vein. He believed that if we add
6 anastomosis here -- anastomosis is effective for causing evening of high
7 blood pressure, which is not the case. The fact is because the blood goes
8 into the vein, that this vein reacts as it forms.

9 Keeping that in mind, I invented this shunt. It is called a hybrid
10 arteriovenous shunt. I realized that I can solve this long-felt unsolved
11 problem if I wired putting the blood into the vein but directly into the heart.
12 The heart is a muscular organ, and there the neointimal hyperplasia does not
13 occur. And therefore, the background of the invention. But why it is
14 unsolved problem?

15 So my invention essentially consists of the graft connected to the artery, and
16 then I connect this graft with the catheter, which goes into the right side of
17 the heart. This catheter and the graft is connected by a cuff by anastomosis.
18 This circuit line. So essentially the art has three components -- graft, cuff
19 and a catheter -- going into the right side of the heart.

20 JUDGE MCCARTHY: Dr. Khan, can you tell me what role the cuff plays
21 in a preferred embodiment of your invention?

22 DR. KHAN: Yeah. The cuff -- the catheter is 1 millimeter smaller than the
23 graft, and the cuff is 1 millimeter surrounded. So the cuff is sutured to the
24 graft by sutures so that the cuff and the graft, they fit together. That is how
25 they created it.

26 Now, my invention has three independent claims -- Claim 1, Claim 13 and

1 Claim 17. And the rest of the claims are dependent. Claim 1 describes the
2 hemodialysis apparatus. Three parts -- graft, cuff and catheter. The Claim
3 13 describes that this is a hemodialysis apparatus, therefore purifying the
4 blood of the patients.

5 Notice 17 is the broadest claim, which describes the three parts and how it
6 works like this. The blood is taken from the graft with needles. This needle
7 goes into the graft, it goes into the dialysis machine, and from the dialysis
8 machine, the pre-heart blood goes back and then gets deposited in the right
9 atrium.

10 Now, the Examiner, he relied upon three prior arts to prove that my claim is
11 obvious. That is what the Examiner did.

12 JUDGE PATE: Okay.

13 DR. KHAN: The Squitieri, Parks, Trerotola and Twardowski. Now, I'm
14 going to go to Claim 17, and the Claim 17 she rejected over the Squitieri,
15 Parks and Twardowski.

16 Now Squitieri's art suggests -- the Squitieri art, that he has three components
17 to his invention. One is the graft, second is the cuff and third is the catheter,
18 which remains in the vein. So Squitieri did not name the veins, what vein,
19 because he is pushing it -- according to his diagrams, he is pushing it into the
20 veins, and the veins here, here and here, but he does not cause this line here,
21 so it doesn't go into the heart.

22 The Claim Number 1 of Squitieri states that the catheter remains adaptive
23 within the vein so that the blood flows from the dialysis machine after the
24 purification into the vein. That is Claim Number 1.

25 Claim Number 8 of Squitieri states that the blood -- again, the catheter is in

1 the vein and the blood after the dialysis goes into the vein. And Claim 16
2 makes it very clear the catheter section to be adapted within the vein so that
3 the blood from the machine goes directly into the vein. It is three claims that
4 Squitieri makes very clear that the catheter remains in the vein and the mode
5 of operation is that the blood flows into the vein.

6 Whereas in my patient, in the claim of the invention, the mode of operation
7 is different. That the blood flows from the machine after dialysis and it goes
8 into the right side of the heart so that there is no chance for any neointimal
9 hyperplasia to develop.

10 JUDGE MCCARTHY: But, Counsel, doesn't Figures 7 and 8 show the
11 catheter extending at least into the large vessels immediately above the
12 heart?

13 DR. KHAN: Above the -- that is vein.

14 JUDGE MCCARTHY: But wouldn't you then get at least some injection of
15 the returning blood into the -- at least the upper chambers of the heart?

16 DR. KHAN: No. But Squitieri says that the blood will go into the vein. It
17 will go around the catheter. It will go around the catheter and into the vein.
18 That is what he says. He does not mention anything about the heart.

19 So what the Examiner stated that there is a teaching in Squitieri's art that this
20 may suggest to go into the heart. To respond to that question, I said that
21 would amount to modification of the heart because Squitieri's patient is
22 made based on blood going into the vein, not into the heart.

23 So if there is any citation or modification, then the Examiner has to show me
24 if there is some teaching in Squitieri's art that his art be modified. And she
25 responded, I disagree. This is the Examiner's Answer.

1 JUDGE PATE: We were looking at this Figure 7 in Squitieri, and it looks
2 like that at least that goes into the superior vena cava. Is that not correct?
3 Number 66 goes down in there.

4 DR. KHAN: Let me get the pictures out. Figure 7?

5 JUDGE PATE: Yeah, Figure 7.

6 DR. KHAN: Figure 7 shows that the catheter is in the vein in the superior
7 vena cava. It is above the heart.

8 JUDGE MCCARTHY: Does that -- would that vein still suffer the same
9 detriment of a thin wall that you would find with the other veins?

10 DR. KHAN: These are thin walls. All the veins are thin walls. They all
11 have this reaction of hyperplasia. What the Examiner asked is, is -- I'm
12 wondering if you modified this art, is there anything in Squitieri's invention
13 saying that there would be some modification? She did not answer that
14 question for me.

15 In the third question she says is that there is some teaching in the law that
16 would be more deviations for modification. So she did not answer my
17 question very clearly. Is there any modification in the prior art or not?

18 She introduced it regarding the question of the mode of operation. The
19 Examiner believed it is the diameter which causes the change of mode of
20 operation. She was not clear in that. She said it incorrectly. She believes
21 the mode of operation is dependent upon the diameter of catheter.

22 What I said in my Brief is that is dependent on the length of catheter where
23 the final end of the catheter will go so that the blood will be ejected off of
24 dialysis at that point. That is the mode of operation. The Examiner
25 incorrectly said that it is the diameter of the catheter which determines the
26 mode of operation.

1 JUDGE MCCARTHY: Counsel, does Squitieri specify what the length of
2 the catheter that he is using is?

3 DR. KHAN: No, he did not. He only said that the catheter shall stay in the
4 vein. That is it. He did not say anything.

5 JUDGE MCCARTHY: Is there any particular reason why the catheter in
6 Squitieri would have to be one particular length as opposed to another?

7 DR. KHAN: If you're going to show the catheter into the vein here, then he
8 puts it here, he puts it here. You see the three diagrams there? In Diagram
9 7, he put the catheter near in the superior vena cava. And in Diagram 8, he
10 puts it in the subclavia vein. That is this vein. And then in Diagram 9, he
11 puts it here -- about here, you see, in the superior vena cava.

12 And he does not name the veins. He puts the catheter at different places
13 without naming them.

14 Then the Examiner introduced another reference.

15 JUDGE MCCARTHY: Counsel, if I might step back to Squitieri one more
16 time, is there -- if there is nothing in there that specifies what the length of
17 the catheter needs to be, wouldn't it be possible that if you were to use a
18 catheter that would, say, fit into a vein for one patient, that it might be
19 adapted to extend into the right atrium for another patient?

20 DR. KHAN: No. Because he is very specific that his catheter remains
21 within the vein. It does not go into the heart. That is how I dealt with my
22 invention.

23 Without naming the veins, the Squitieri -- my invention is different in the
24 cuff. He uses two little wires. And those two little wires have two uses. In
25 one little wire he takes the blood out, and the other little wire he puts the
26 blood in.

1 So mine is not like that. I don't use little wires for taking the blood. I use
2 the graft to take the blood out. So that is another point of difference between
3 his invention and my invention.

4 JUDGE MCCARTHY: Counsel, does that appear anywhere in Claim 1 or
5 Claim 17 that, if I understand correctly, you use the graft to remove the
6 blood?

7 DR. KHAN: Yeah. It is in Claim 17. Claim 17 of my invention.

8 Without naming the veins, the Examiner introduced another reference of
9 Trerotola. But he did not reject that in Claim 17. He used the Parks
10 reference. What Parks' cuff is, is -- he says that Parks' cuff is equal to my
11 cuff.

12 Now, what Parks -- this is a gastrostomy tube. And his gastrostomy tube is
13 used for feeding the patients. And inside this, there is a little structure inside
14 it. In that little structure, the catheter fits. This is called the catheter and this
15 will hook to the feeding border and then the feeding goes into the stomach.
16 And she says that this little structure inside of this tube is equal to my cuff. I
17 said that this little structure has to go inside this tube. And if I put that --
18 firstly, this is a different system not in and of this art. It is called the
19 gastrointestinal stomach. And mine is in the vascular.

20 And if I took this cuff and put it here into this, then the blood flow in the
21 graph could stop. Just like putting a pipe, and in the pipe you put a stone.
22 The same thing happens here. If I put here into this tube, then the blood will
23 not go and the shunt will not function. So it will lead to the destruction of
24 the function of the invention of mine and she also quoted Squitieri.

1 So in both cases, the function of the shunt will be destroyed. So therefore,
2 this art is not able to overcome our invention or Squitieri's invention. This is
3 what I discuss in my Brief.

4 Then the third reference she made with respect to Claim 17 is Twardowski's
5 reference. What Twardowski's reference is, is it is a catheter, and we call it
6 this kind of catheter. This catheter goes in the heart, comes out and partly
7 goes under the skin. It has two limbs, one and two. So it is a double lumen.
8 And my catheter and Squitieri's single lumen. So I said that this couldn't be
9 combined with the Squitieri art because both have different lumens. This is
10 one lumen and Squitieri's is a single lumen and, therefore, they cannot be
11 combined. One skilled in the art will not combine the two because they
12 would not fit together.

13 The Examiner quoted a reference saying that it is not essential to combine
14 the two arts. It is what the teaching of the art is. Teaching is that Squitieri
15 puts the catheter into the right side of the heart. So if we cannot combine
16 this with the Squitieri art, then the claimed invention will not reproduce. So
17 when it will not reproduce it, it is not obvious under Section 103.

18 Then this catheter, that is the dialysis in a different way than the claimed
19 invention. So here the blood is taken from the vein, put to the dialysis
20 machine and goes back to patient after purification. But in our art, it is
21 substantially different. In my art, the blood comes from the artery not from
22 the vein for dialysis. Secondly, in my art the blood is flowing continuously.
23 Here, the blood does not flow continuously. It is stagnant when it is not in
24 use. Thirdly, that this catheter produces a lot of complications. It is hanging
25 outside on the patients like this, so it produces infection and it blocks easily.
26 These are the drawbacks of this catheter.

1 Now, comparing the results of this catheter with my invention. So
2 comparing this and this, the studies have been very clear that this catheter
3 has an infection rate high, whereas my invention has low. Secondly, the
4 patient success of this is low; it doesn't -- it clots. And patient success of
5 this is high. The Examiner acknowledges these two facts.

6 And then the other factors which are very important is, how does the prior
7 dialysis perform? And that dialysis is performed by a Kt/V . K represents
8 the blood flowing through the shunt by minute multiplied by the time
9 divided by the volume of the body. It gives us an index, and the index is
10 from National Society of Kidney Foundation, Quality Improvement
11 Initiative, and it is called $K/DOQI$, states that if it is 1.4, then the dialysis is
12 optimal for purification. If it is high, it is better for the apparatus.

13 So in our invention, it was found 1.7. So that means that our art performs
14 superior than Twardowski's art.

15 JUDGE MCCARTHY: Would a doctor in your field have been able to
16 predict had they known of your system that your system would perform this
17 much better?

18 DR. KHAN: I do not know. It was an unexpected finding to me. It was far
19 superior.

20 JUDGE MCCARTHY: But you're saying that this is something that a
21 doctor in your field would not necessarily have expected?

22 DR. KHAN: I did not know at the time when he invented the invention that
23 ours would be superior. I didn't know that. But it came from the studies.
24 And the studies showed that it is 1.7.

25 And this has an impact of the mortality of the patient. If I have 100 patients
26 with Kt/V 1.7 and then I use another device where the Kt/V goes 1.4 and this

1 is 1.42 the mortality decreased is 7 percent. That means 16 percent of the
2 patients will die within a year if their Kt/V went down. This Kt/V shows the
3 performance of the dialysis apparatus.

4 JUDGE MCCARTHY: But based on your experience, this is an unexpected
5 result?

6 DR. KHAN: This is an unexpected. The mortality. I did not know it
7 predicted the mortality of a patient.

8 So further what the study showed that this catheter produces this vein
9 structure. You see this is the veins through here and they go in this and then
10 he causes stenosis of the vein. What he did, he studied those patients with
11 several obstructions and he found that that obstruction can be fixed by
12 angioplasty and then we put this catheter here. We can give them a shunt
13 dialysis. And shunt dialysis is superior dialysis. 80 percent of the cases
14 were successful when he did that.

15 The problem with neointimal hyperplasia can only be solved by my catheter,
16 not by other inventions. The Squitieri, the Twardowski, the other authors,
17 nobody will solve this problem. And at this time, we use the shunts
18 connecting the graft to the heart. It is a common operation. But because the
19 claimed invention we came to use last year, and it has shown very superior
20 results.

21 I think this may be -- in the future, use for all high-risk cases. But most of
22 this is of vena cava. If you read the graphs and the articles here, they clot,
23 they fade, 80 percent of the cases. And this would be the best, superior.

24 JUDGE PATE: Dr. Khan, we have already run over time here. So I'm
25 going to cut you off right now unless we have any more questions.

1 JUDGE MCCARTHY: Just one comment. We appreciate the effort you put
2 into your presentation today, but the items that you've shown us will not be
3 part of the evidence in the record. We have viewed them and we understand
4 them, but they will not become a permanent part of the record.

5 DR. KHAN: I came to point out some of the points that were not very clear
6 in the responses of the Examiner.

7 JUDGE MCCARTHY: Yes, we do appreciate it.

8 DR. KHAN: That is what I came here to explain.

9 JUDGE PATE: Thank you, Dr. Khan. We're going to take this case under
10 advisement.

11 DR. KHAN: Thank you.

12 Whereupon, the proceedings at 9:26 a.m. were concluded.
13